



# THE SERVICE ROADMAP **OF THE WILD GROUP**

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# You can rely on our support

11 service modules - 11 possibilities to launch your products onto the market quickly and in a more optimised, cost-effective way.



Josef Hackl Managing Director CEO WILD Group



Wolfgang Warum Managing Director CTO WILD Group

Being a technology partner without its own products, the focus on services is deeply rooted in the WILD Group's DNA. A common thread runs throughout all phases of our product development process: the services we provide to our customers and which give them a decisive competitive advantage. Five years ago, we compiled these into a Service Roadmap (SRM) for the first time. A lot has happened ever since. Not just with regard to innovative technologies and international supply chains, but also in terms of regulatory matters, our process landscape, and new, agile methods. Our customers' requirements are undergoing constant change and the SRM has developed accordingly, just like a "living organism". It encapsulates all our knowledge and skills. It delivers answers to the many questions that may arise during product development, supply chain design, transition to serial production and even during the repair & refurbishment phase.

What makes our company stand out is the modular combination of services in development and manufacturing. No matter what stage you currently find yourself in: WILD will deliver precisely the service that you need at a given moment. How do we manage that? By listening very carefully to our customers and trying to understand their needs down to the smallest detail. We align our services to the current requirements of the market and adjust them on a regular basis.

For this reason, some of our service packages have been modified in recent years. We have partly consolidated some of them and added some new ones. Now we want to find out what the future holds together with you. Let us continue our dialogue in even greater depth, to stay on the pulse of the market, both actively and proactively. Tell our SRM topic promoters exactly what you need from your own perspective. That is the shortest and most efficient way to create innovative products.

Thank you for your confidence in us.

Josef Hackl & Wolfgang Warum



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# WILD

# ENGINEERING

# **THE NEW PRODUCT**

Regardless of whether you are right in the middle of the development process or are still searching for ideas, we will develop precisely what you need.

When should you consider outsourcing in development? As a rule, when you exceed your own development or manufacturing capacities, when resources are missing or knowledge surrounding the next technological steps is not fully available. Renowned manufacturers in medical and optical technologies have already taken this decisive step and entered into a development partnership with the WILD Group.

Companies can get on board at any stage of development, regardless of whether they request the complete package from the idea to the serial product - or just selected modules. Throughout the entire product creation process, WILD's engineering experts guarantee high-quality consulting services, cross-industry approaches, in-time production of functioning prototypes and a profound knowledge of the relevant norms and standards. From the very beginning, the focus lies on a feasible serial product that meets the customer's expectations with regard to quality, function and cost.

### **One-stop interdisciplinary development**

This is guaranteed by the simultaneous engineering approach followed by WILD which permanently aligns different disciplines. Recently, the company achieved exemplary success with the development of a highly sensitive surgery stand for endoscopic and invasive interventions. Everything from the electronic and mechanical parts to the software had to be redesigned from scratch and perfectly adjusted to the medical-optical equipment to be mounted on the stand. The sticking point is that the stand is not only capable of bearing the load of the equipment, it must also balance it without vibrating or oscillating. This is why the software plays a crucial role in reading out the sensors. "Another challenge consisted in the high project dynamics and the fact that we delivered everything from a single source, from the consideration of the corresponding regulations and concept development to pilot production", explains Development Manager Michael Reissig.



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# **CO-ENGINEERING**

# **DEVELOPING HAND IN HAND**

We will support your development team with the necessary far-sightedness and perspective. We can get your products very close to serial production at an attractive cost.

Maintain the big picture in development while planning every detail. Deliver right-first-time quality in production. In order to achieve this, more and more innovative companies are taking advantage of the proven concept of co-engineering practised by WILD.

After all, when you make the right decisions at an early stage, you can avoid mistakes in later project phases. "The advantage is that we assess the products from the perspective of an industrialiser and keep an eye on their suitability for serial production from the very start. We make sure that they can be produced state-of-the-art, cost-efficiently and with a high level of quality stability", explains Development Manager Michael Reissig. As a technology and implementation consultant, WILD contributes its know-how in mechanical manufacturing and programming, industrial serial assembly, quality assurance and supply chain management.

# Quick transition to serial production

The fact that this early involvement of WILD experts can reduce the time from prototype to serial production by months is demonstrated by the fully automatic pipetting system of BRUKER Daltonik. During the creation of this innovative system, which can identify micro-organisms on the basis of their molecular footprint, the customer's developer team spent a considerable amount of time on site at WILD working intensively with the manufacturing team.

As a result, the two managed to convert new ideas and models into prototypes in a very short time.

"This face-to-face cooperation is essential for us. After all, knowledge transfer does not take place merely through drawings, specifications, emails and phone calls, but also through shared experiences and trustful cooperation", stresses Dr. Martin Schürenberg, Development Project Manager at BRUKER Daltonik.



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# **RE-ENGINEERING**

# THE MODERN, PROVEN PRODUCT

Successful re-engineering can herald an affordable and reliable new lease of life for your product.

How can you manage to keep a proven product profitable and attractive for the market's requirements in the long run? "By keeping what works well and focusing on the many small things that need improvement", says WILD Medical Technology Project Manager Erwin Meritschnig. How much successful re-engineering can achieve is shown by the filter module optimisation project that WILD was assigned by Roche Diagnostics International AG. The objective was to identify the cost potential and the design flaws in four filter module versions used in a molecular biology analysis device and to address these issues with clever design optimisations.

"We were instructed not to intervene with the concept and the optical path. The focus was on re-designing the mechanical part. Therefore, we concentrated on reducing the processing steps and on simplifying both parts and functions", Meritschnig explains. By applying a total of 16 measures, including a re-design of the motor mount, WILD managed to cut costs by EUR 300,000 per year with the same production volume. The changes applied to seemingly simple things. In sum, however, they contributed significantly to a stable manufacturing process with a reduced need for inspection and shorter assembly times.

"As a result of the close cooperation with WILD and the common pool of experience, we managed to implement the re-engineering project successfully and to even exceed the envisaged targets. I particularly appreciated the open and transparent communication, the structured approach and the development and manufacturing expertise contributed by WILD from the initial concept to the release for serial production", summarises Stefan Vollenweider, Development Engineer Thermal Solutions at Roche Diagnostics International AG.



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# VALUE ENGINEERING

# **IN SEARCH OF ADDED VALUE**

WILD supports you in achieving cost-optimised, value-optimised development of your products and designs profitable added-value processes.

Targeted value engineering across the entire product development process is one of the most important tools for making your products successful in the long run. WILD has therefore installed a systematic process that tracks down potential cost savings in each phase. In doing so, there is no such thing as a standard procedure. "Depending on the situation, we choose the best-suited method for our customer", says Markus Aichwalder, Development Project Manager. "In addition, we not only focus on the costs alone or on individual cost drivers. Using a cost function matrix, we also calculate the value of a product or of individual functions."

How much added value this brings can be demonstrated by the example of a medical technology customer who approached WILD with an idea for the cleaning of endoscopes that is completely novel on the market. "In this particular case, we became involved at a very early stage and calculated the functions and their costs together. The advantage of this approach: Deciding whether a function is actually necessary or it can be covered by an already existing one is becoming an increasingly important consideration. By applying this design-to-cost methodology, we avoid over-engineering and, ultimately, unnecessary costs", explains Markus Aichwalder. We also took into account the issue of the material, the manufacturing process of the first prototypes and much more besides. All in all, the approach we chose helped determine the manufacturing costs and the customer now knows how they can position their future product in the market.

In the case of a finished product, WILD resorts to conventional cost-down methods to identify potential cost savings. "In this

case, we first determine what cannot be changed at all and where flexibility is possible. Where the customer does not want to introduce many changes to the product, we carefully examine the supply chain and look for possible simplifications to save process costs", says Aichwalder. Like a firewall, the WILD experts can intercept costs in time on the basis of a current state analysis, thus drawing attention to every detail.



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# LIFE CYCLE ENGINEERING

# **PRODUCTS ALWAYS FIT FOR USE**

Life Cycle Engineering helps to reduce risks, extends the life cycle of your product, reduces costs and guarantees a return on your investment for a longer period.

This is the ideal "anti-ageing" solution that helps your product keep up with the market requirements in the long run: Life Cycle Engineering. This is of particular importance with equipment involving a high level of investment and difficult registration procedures. As your technology partner, we analyse your products and ensure a proactive selection of components from the very start in order to avoid any early discontinuations. Where necessary, our team also defines second-source parts and designs products in a manner that allows you to implement your product in small initial quantities and later in large volumes. We always keep a watchful eye on software updateability and we use industrial PC platforms with long-term delivery guarantees.

Regular product upgrading is necessary for your product to maintain a solid position on the market in the long run. WILD will help you achieve that. Continuous improvement processes help us point out to alternatives and integrate the latest technologies. In the case of end-of-life components, we can react in time and help you select new components and carry out risk assessment and verification for them. In addition, we also take care of stockpiling and the proper storage of last-time-buy parts.

### Keeping an eye on the future

The Heidelberg Retina Tomograph (HRT) demonstrates how life cycle engineering can help successfully establish a product on the market over decades. This confocal scanning laser system is considered the gold standard in modern glaucoma diagnostics and continues to be the undisputed market leader to this day. Since the systems partner took over the complete production of the HRT more than 20 years ago, they have carried out several upgrades, including an adjustment of the lens, which significantly reduced the wear and tear of various mechanical parts. Moreover, they eventually had to replace a linear guide unit which was no longer available, adjust the electronic systems and fine-tune the laser. Due to the introduction of the medical technology standard EN 60601-1, it also became necessary to adjust a power supply unit, which in turn resulted in the replacement of various mechanical parts.

augroppe

Labeling



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# REGULATORY AFFAIRS

# THE SAFETY PACKAGE

Tread safely on treacherous ground. WILD's stable development, production and quality assurance processes provide certainty in every phase of the product's lifecycle.

Many companies are familiar with the problem: On the one hand, they rely on consultancy firms to support them in regulatory matters. On the other, they resort to the expertise of contract manufacturers and developers for technical issues. Only a few of the latter offer a combination of both. The WILD Group, however, is one of those technology partners who provide their customers with a comprehensive package of services in the area of regulatory affairs.

Especially since its involvement in the manufacturing of medical technology products, WILD has had to respond early to increased requirements. "In the beginning, we also had the feeling that issues such as mandatory documentation were putting the brakes on our work. Today, with the expertise acquired through various projects, we can accelerate the time to market process", says Melanie Täuber. Driven by the MDR and the fact that WILD is increasingly being assigned large development projects, there has been another great leap in quality in the last two years. Today, dedicated system architects and quality engineers are there to support customers from a wide variety of industries in managing their increased documentation requirements. According to Melanie Täuber, it is important to keep in mind that "regulatory affairs begin with the product idea. Those who bring along experience and expertise in this area from the very start are much better positioned."

WILD itself is an FDA Contract Manufacturer and certified according to ISO EN 13485 and can thus support customers already at the start of the product lifecycle, e.g. in identifying and evaluating the relevant standards and guidelines, with risk management according to ISO 14971, or with technical documentation, including design history. In future, everything ranging from general safety requirements and risk analysis or risk requirements to validated and certified products will be modelled in a new product lifecycle management tool. It will then become significantly easier and safer to track modifications.



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# PROCESS ENGINEERING & VALIDATION

# **RAISE YOUR QUALITY LEVEL**

Robust. Valid. Reproducible. The WILD Group's sophisticated process engineering guarantees stable production processes, from development to serial production. The result: top quality from the first to the last product and a reduction of the costs and risks.

Be it in medical products or laser assemblies - the quality level in the market is constantly rising. Not least due to costly complaints, the desired target is zero defects, even if it is not possible to control every detail in production 100 percent due to economic considerations alone. WILD's solution: sophisticated process engineering that guarantees stable and safer production and lives up to the highest quality requirements.

The cornerstone of this process stability is an in-depth Failure Modes and Effects Analysis (FMEA), which addresses issues such as: Which error can occur? What would it trigger? How high is the probability that this error will occur or that it will be discovered? "This analysis is essentially a mathematical model. When an area sounds the alarm, we introduce further measures for quality assurance", says Emmerich Kriegl, Head of Quality Management at WILD GmbH.

After that, we always launch a process validation when we don't have the possibility to fully verify a critical process output for the product's function as part of our added value. This is necessary, for instance, in the case of relevant gluing and welding processes. For this reason, we ensure an adequate specification, define clear process limits and deliver objective proof of the stability and robustness of processes on the basis of statistics", Kriegl explains.

At WILD, process validation is carried out in three stages: installation qualification (IQ) ensures the proper

implementation of the process environment and the necessary infrastructure. "Subsequently, we use operation qualification to explore the limits by carrying out various tests within and outside of the specification limits. This allows us to precisely define the suitable process parameters," Kriegl adds. In performance qualification, the company furnishes statistical proof that the process functions in a stable manner within the predetermined limits. "All in all, this package provides our customers

quality characteristics and we deliberately want to examine a process as to its weaknesses, however, we very often find improvement options that ensure greater stability. As a matter of fact, we often help our customers achieve a genuine leap in quality."

A very good example of that is a set of magnifying spectacles that WILD has been producing with zero defects for more than five years. "The customer is delighted with our quality assurance project because prior to transferring production to WILD, they regularly had problems and received negative feedback from the market." In the case of a GMP-compliant scanning laser imaging module for the American market, a customer from the medical technology industry also resorts to WILD's expertise. "The equipment qualification and validation implemented at WILD guarantee stable production and quality assurance processes, also offering regulatory safety", says Kriegl. Therefore, the fact that these products can be placed on the American market without any difficulties is largely owed to WILD.

As part of the conception of a quality assurance concept, WILD also offers the development of suitable test methods which are reviewed using method validation prior to approval for serial production. For instance, after determining the exact requirements, WILD implemented a validated test stand for a renowned company in the field of 3D measurement, imaging and implementation solutions, which guarantees the quality of the products.

with compliant processes, including the necessary documentation. Moreover, we speak the same language, which is based on objective documents and thus defines a common level," says Kriegl. By the way, this also applies to any modifications to the product. If the customer carries out such modifications, WILD performs a re-evaluation so that the process can continue to function perfectly.

As part of an FMEA, WILD can also develop a quality assurance concept for the customer, creating a tailored package with efficient assembly and test instructions. This is of great importance not only for medical technology companies, which rely on regulatory safety for audits and inspections. "Each and every one of our methods in process engineering is money well-invested", stresses Emmerich Kriegl, "since this significantly reduces the risk of error". "In the beginning, the coordination work was slightly more complex. When we start looking into certain



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# PROTOTYPING

# FAST-TRACKING FROM IDEA TO SERIAL PRODUCTION

Using our experience in the development of mechanics, electronics and software, combined with our expertise in conventional and additive manufacturing processes, we can turn your idea into a fully functional device in a very short time.

Those who are capable of quickly converting ideas into prototypes to test their application can significantly accelerate their development process and thus gain a decisive competitive advantage. Functional prototypes are indispensable, not only in engineering. They also represent important decision-making tools in value analysis or during CIP. From concept creation to various manufacturing techniques, WILD knows the ropes in all technologies required for the development and production of highly complex prototypes.

The technology partner offers its customers a dedicated production line, allowing them to implement mechanical prototypes within a very short time. "We can also deliver the electronics and the PCBs within just a few weeks, so as to launch the first tests with a prototype board. We also programme the corresponding software in modules to be able to quickly move on to the test phase as well", stresses Johannes Schmidt, Material Transfer Manager. "All in all, the quality and also the choice of the right designs and materials are crucial for a smooth transition to serial production."

### Putting ideas to the test, right away. Implementing improvements fast.

For instance, WILD created a demonstrator for a portable respirator for its long-standing customer Carl Reiner in just a few months. This inexpensive and crisis-proof device based on the customer's own technology can be operated without electricity and only needs compressed air or an oxygen bottle to work. It is easy to use, so that the patient can be given proper respiration even on top of a mask or while intubated. "We developed an industrialisation concept together with



Carl Reiner, adapting both the technology and the design of the device to the latest standards. Using rapid prototyping technologies - parts of the casing were 3D-printed - it was possible to quickly deliver a prototype which has already received very positive feedback in tests.



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# PRODUCTION TRANSFER

# MOVING PRODUCTION SAFELY AND EFFICIENTLY FROM A TO B

Greater flexibility, cost advantages, more freedom to focus on their core business and access to additional competencies are the reasons why many WILD customers are focusing on product outsourcing as a strategy.

Outsourcing production processes is a highly complex undertaking, during which many more things need to work smoothly than just the mere technical implementation. Government requirements, regulations, proper documentation, a structured material transfer management and the issue of speed call for an experienced hand. With WILD, you have a technology partner at your side who is well-versed in quickly, efficiently and flexibly integrating complex projects into its operations.

Such projects include adjusted commissioning systems, a stable material supply or the optimisation of existing products: WILD can handle the entire range of the tasks involved and can take these over in a very short time", stresses Manfred Gallé. The production transfer management system process plays a quintessential role in this. It serves as the guiding principle used by the project team to work itself through tested and proven check lists. All details in the areas of supply chain, assembly, material supply, infrastructure, tools & resources, as well as training are planned and implemented in the above process. Material transfer, however, is not just about a stable supply. WILD also examines whether the documents are up to date and whether the components delivered are according to the specifications. "This ensures structured processing of these topics and guarantees compliance with the regulatory requirements."

### **Outsourcing of product updates**

The best example for this is a medical technology product. The customer was faced with the challenge of fitting a new handpiece to a laser treatment console already in use by its customers. In their already strained capacity situation, they were unable to cope with the additional organisational and assembly effort. This is why

WILD had to coordinate the project details within just a few days. "Our staff travelled to the customer at short notice to analyse the assembly process and to draw up the project plan." After that, they disassembled around 200 devices from different countries at our site, installed the new component groups and carried out the necessary final tests", Gallé explains.



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# WILD

# SUPPLY CHAIN DESIGN

### **BE PROACTIVE**

Is your product demand volatile or well predictable? WILD has a suitable solution portfolio available for every requirement.

Short-term changes in demand, highly fluctuating forecast figures or a shorter time to market - the general setting of supply chain management presents a challenge for every company. "There is no one size fits all solution. Therefore, we precisely examine the requirements of each customer and then build a tailored supply chain for them", says Christian Rabitsch, Head of Supply Chain Management at the WILD Group.

# Maximum availability & responsiveness at the best possible cost

The ultimate objective is to react to fluctuations in demand without any delays. The key to such responsiveness is a whole toolbox of retrieval and ordering models offered by WILD. "Our team is capable of redesigning systems from scratch and breaking the mould of old practices. As a result, we can react specifically to customer requests and create intelligent solutions that provide more flexibility at a lower risk", says Rabitsch.

The options range from simple orders with a fixed delivery deadline to rolling orders coupled with a Vendor Managed Inventory (VMI), where WILD is in charge of managing the customer's warehouse. "We have products for which we deliver 10 pieces per year and those with an annual volume of a few thousand pieces. Depending on the general conditions and the criticality of the product, delivery availability is secured accordingly. The range of possibilities is very diverse; it begins with safety stocks at component level with the sub-suppliers and extends to process and inventory monitoring along the supply chain", stresses Rabitsch.



For instance, WILD has recently implemented a rolling order system with individual release horizons at component level for one of its medical technology customers. By eliminating the general transition between subsequent orders, the customer now benefits from high supply security and a low loss rate in the supply chain. Depending on the customer's target priorities, the horizon can be adjusted differently to individual components with regard to material release and production go-ahead.

In addition, WILD employs a Supply Chain Optimization Tool, i.e. simulation software that models all agreed parameters and allows for the synchronisation of the supply chain between the customer, WILD, and the supplier. As a result, it is possible to optimise the supply chain on an individual component level and to design a cost-effective, intelligent solution with the shortest response and replenishment times possible.

### WILD takes over supplier management

For years now, WILD has relied on a standard-compliant, risk-based supplier qualification to ensure that its customers can rely on stable processes on the supplier side. This creates regulatory certainty and helps cut costs. The supplier evaluation, development and audits carried out by WILD take the effort involved in all these processes off the customer's shoulders. Depending on the risk, even the highest requirements at component level can be secured and thus permanently met through the corresponding process capability and first sample methods.



### A path to holistic compliance

Another area of responsibility where the WILD Group takes a lot of burden off the customer is the strict monitoring of the respective rules. Obtaining and managing all the information ranging from raw material sources to listed substances requires a lot of time and resources. WILD has created a dedicated structure for this purpose so that customers can put all measures and processes in place to ensure compliance with the rules without having to build up know-how and capacities themselves.



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# REPAIRS & REFURBISHMENTS

# AS GOOD AS NEW

Full exploitation of a device's lifecycle is not only sensible from an economic point of view, the aspect of sustainability is also increasingly coming to the fore.

Though numerous devices are becoming ever more complex and product lifecycles are getting shorter, a trend toward general overhauling is on the rise. For good reason: Consumers are realising that the repair, refurbishment and updating of equipment already used offers ecological advantages and saves money. Manufacturers are also increasingly appreciating that repairs and refurbishments can help extend the lifetime of their products.

"Currently 90 to 95% of customers are ordering such services with us. In addition to conventional repairs, they mostly take advantage of services such as software and hardware updates", explains Stephan Payer, Head of Business Unit WILD Electronics. Following these updates, the products correspond to the state of the art. In addition, some products must undergo regular calibration. Since the WILD Group already carries out calibration during the production of these devices, it is only logical to put recalibration in the hands of the technology partner.

"For our customers, the decision to outsource repair and refurbishment services is based on organisational and economic considerations", says Payer. "As a manufacturing partner, we exploit synergies for the benefit of our customers. After all, the physical infrastructure and the staff required for these processes are already in place. Moreover, it is possible to cost-effectively manage spare parts along the away and assembly documents and test reports are always available in the latest version. In addition, we either take care of the corresponding line clearance or we set up dedicated service and refurbishing workplaces in the direct vicinity of the serial production." WILD can thus make the best possible use of the resources available while at the same time complying with the applicable regulatory provisions that require separate workplaces for serial production and repair, especially with medical products.



For instance, a maker of IVD devices entrusted the experienced technology partner with more than just the manufacturing of various assemblies: when repairs are necessary, WILD also takes care of the replacement and the return of the device to the product cycle as a new-device equivalent. In the case of revision changes, too, devices currently in operation are replaced accordingly and brought up to the state of the art. As a result, all assemblies correspond to the latest stage of development.



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# NTEGRATED NETWORK WIN

# QUALIFIED EXPERTS WORK WITH AND FOR WILD.

The WILD Integrated Network (WIN) is a well-established, constantly evolving network operating in coordination with us so that you can reap the benefits. We have created a network of experts around 12 Technology Roadmap topics, 11 Service Roadmap topics and 6 fields of competence. By supporting us, they also assist you in your projects.

# WILD

# HIGH TECH, DEVELOPED AND MANUFACTURED AT YOUR REQUEST

THE WILD GROUP IS A PARTNER AT YOUR SIDE WHO EFFICIENTLY, QUICKLY AND SAFELY BRINGS YOUR PRODUCTS TO SERIAL PRODUCTION AND DELIVERS ACCORDING TO VALIDATED PROCESSES IN THE LONG TERM.

### **Fascinating products**

Novel laboratory analysis devices, surgical equipment, lighting for endoscopic interventions, therapeutic devices or medical high-performance lasers: wherever there is demand for optical technologies coupled with mechanics and electronics, the technology partner can fully exploit its potential.

The WILD Group develops and manufactures exclusively on behalf of its customers. In doing so, it has one clear edge appreciated both young companies and established market leaders: the combination of optics, electronics, precision mechanics and application software.

# Contract development and manufacturing at the customer's request

WILD is a one-stop solution with services ranging from product development and an individually adjusted supply chain to a strict quality management according to EN ISO 13485 and ISO 9001 and process-stable, valid and FDA-compliant production. Thanks to the Service Roadmap, which comprises a total of 11 service modules, even combinations of individual modules from this process chain are possible. Moreover, the WILD Integrated Network offers WILD customers a benchmark in costs, lead time, alternative procurement channels and warehouse logistics.

# Shaping tomorrow's technologies today

Those who want to master new technologies early and in their full complexity, and bring forth innovative solutions for the future must stay abreast of developments. The WILD Group has developed a Technology Roadmap specifically



for this purpose. It ensures that the technology partner remains fit for innovations and their implementation in as many as 12 technology areas. Ultimately, the objective is to keep an eye on the big picture while working with a love for detail.

The WILD Group operates at four sites in Austria and Slovakia with a workforce of almost 500 employees.

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**Owner and publisher:** WILD Group, Wildstraße 4, 9100 Völkermarkt, Austria T +43 4232 2527-0, E-Mail: sales@wild.at **Responsible for the contents:** CEO Josef Hackl, CTO Wolfgang Warum

Editorial staff: Andrea Patterer und Sabine Salcher Photos: WILD, Photonic, Shutterstock

# THE WILD GROUP

The WILD Group is comprised of the WILD brands which are established in Völkermarkt and Wernberg (Austria) and Trnava (Slovakia), as well as Vienna-based Photonic. The technology partner develops and produces optomechatronic systems for medical and industrial applications as well as optical technologies exclusively on behalf of its customers. Approximately 500 staff members are always the first choice whenever precision and reliability are called for and wherever innovation takes place.